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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,410	06/04/2007	Valentina Molteni	PAT033827-US-PCT	7171
29490 7590 04/22/2010 GENOMICS INSTITUTE OF THE NOVARTIS RESEARCH FOUNDATION 10675 JOHN JAY HOPKINS DRIVE, SUITE E225 SAN DIEGO, CA 92121-1127			EXAMINER ZUCKER, PAUL A	
			ART UNIT 1621	PAPER NUMBER
			NOTIFICATION DATE 04/22/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPLegal@gnf.org
jclarke@gnf.org
ssesnovich@gnf.org

Office Action Summary	Application No. 10/589,410	Applicant(s) MOLTENI ET AL.	
	Examiner Paul A. Zucker	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/1/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1, 2, and 5, and the species of Example 2 in the specification, in the reply filed on 1 April 2010 is acknowledged. The traversal is on the ground(s) that not all elements of claim 1 are disclosed by Hopwood (US 5,110,348). This is not found persuasive because Applicants have not pointed out what specific element they contend is not disclosed by Hopwood. The Examiner is therefore unable to respond to Applicants allegation. NOTE: The elected specie could not be found by the Examiner in claim 11, contrary to Applicants' assertion, claim 11 therefore does not read on the elected specie and is held withdrawn from consideration. The requirement is still deemed proper and is therefore made **FINAL**. Claims 6, 7, 10 and 11 are held withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

Art Unit: 1621

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

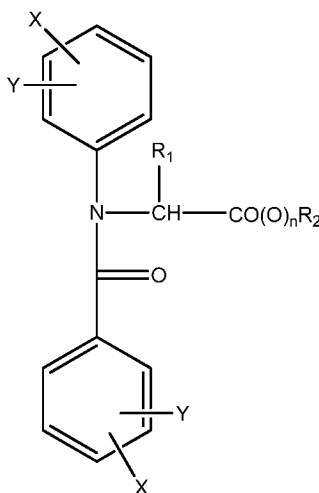
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sogespar (CH 516,523 11-1969, Abstract) or Sogespar (GB 1236091 06-1971).

Instantly claimed are N-benzoyl glycines of Formula I and pharmaceutical compositions thereof.

Art Unit: 1621

Sogespar teaches (CH-Abstract) (N-benzoyl-N-phenyl amino acid derivatives having analgesic and anti-inflammatory activity. Sogespar teaches (CH Column 6, line 35-column 7, line 27; and GB, Patent face, line 15-page 2, line 4) teaches compounds of formula (1) :



wherein, X and Y may be halogen, substituted or unsubstituted alkyl, R₁ may be hydrogen and R₂ may be alkyl or cycloalkyl. The Examiner considers pharmaceutical compositions of the compounds obvious in view of Sogespar's teaching of therapeutic benefit.

The difference between the compounds exemplified (CH Column 5, lines 31-42) by Sogespar and those instantly claimed is that the compounds of Sogespar have a methoxy group on the N-phenyl substituent and are ethyl esters.

One of ordinary skill in the art, however, would have found the instantly claimed subgenus obvious over the genus taught by Sogespar in view of the fact that many of the instantly claimed compounds can be found within Sogespar's genus and have

Art Unit: 1621

similar activity. Thus one of ordinary skill in the art would have been motivated to make the instantly claimed subgenus of compounds in which R_2 is phenyl with a reasonable expectation for success in producing a compound having anti-inflammatory activity.

Thus the instantly claimed invention would have been obvious to one of ordinary skill in the art.

4. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kontani et al (EP 1340750-A1 11-2001) in view of Greene (Protective Groups in Organic Chemistry, 1981, John Wiley & Sons, Inc., Pages 158-169).

Instantly claimed are N-benzoyl glycines of Formula I and pharmaceutical compositions thereof.

Kontani teaches (Page 22, Table 2, entries 1, 4-6, 8 and 9) teaches compounds (IIIa) which correspond to compounds as instantly claimed except for the ester alkyl group in each. Kontani teaches (Page 8, lines 18-27) use of the acid corresponding to the esters as intermediates in synthesis which have been deprotected.

The difference between the compounds of Kontani and those instantly claimed is that Kontani exemplifies the use of the ethyl ester while tert-butyl and cycloalkyl esters are instantly claimed.

Art Unit: 1621

Greene, however, teaches (Pages 158 and 168-169) that simple alkyl esters such as methyl (and presumably ethyl) can be replaced with a tert-butyl group such that one of ordinary skill in the art would recognize the protecting groups as equivalents which could be interchangeably used in a protection-deprotection sequence with a reasonable expectation for success. The Examiner also points out that Kotani, himself recognizes (Paragraph [0033]) the possibility of such modification.

Thus the instantly claimed compounds would have been obvious to one of ordinary skill in the art.

Allowable Subject Matter

5. The following is a statement of reasons for the indication of allowable subject matter:

The elected species is free of art.

Conclusion

6. Claims 1, 2, 5-7, 10 and 11 are pending. Claims 1, 2 and 5 rejected. Claims 6, 7, 10 and 11 are held withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone

Art Unit: 1621

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/
Primary Examiner, Art Unit 1621